

Draft Agenda for Examiner Interview

Appl. No : 10/568,729  
Applicants : Neil Cashman and Marty Lehto  
Filed : July 13, 2006  
Title : "EPITOPE PROTECTION ASSAY..."  
TC./A.U. : 1649  
Customer No : 001059

**Status of Application/Amendments/Claims – restriction based on Kim**

The Examiner has maintained the restriction based on Kim.

- Kim cannot differentiate between alpha-synuclein in wildtype or non-wildtype conformation. Review of claim terms, including "blocking agent" and "detection agent", in relation to prior art.

**Claim rejections – 35 USC 112***Enablement*

Examiner has rejected claims 1-2, 9-17, 20-22, 29-30, 39, 41, 47-49 and 51 under 35 USC 112, first paragraph, as lacking enablement. Examiner asserts, among other things, that Examiner is not in possession of claimed method to detect "all" structurally and functionally undefined polypeptides or epitopes with blocking agents.

- The application provides a representative number of species adequate to enable the claims.
- Review of support for enablement, particularly with respect to the terms "blocking agent", "candidate polypeptide", "target epitope" and "modifying the polypeptide." Applicant will also review support in relation to PrP, other polypeptides and working examples.

*Written Description*

Examiner has rejected claims 1-2, 9-17, 20-22, 29-30, 39, 41, 47-49 and 51 under 35 USC 112, first paragraph, as failing to comply with the written description requirement.

- Review of written description in application beyond that identified by Examiner, for example, description regarding ABeta, SOD1 and alphasynuclein.

**Double patenting**

Examiner asserted that claim 49 is a substantial duplicate of claim 1.

- Claim 1 recites target epitope inaccessible in *non-wild-type* conformation and claim 49 recites target epitope initially inaccessible in *wild-type* conformation.

The Examiner rejected claims 1, 2, 12, 15-17, 20-22, 29-30, 39, 41, 47-49 and 51 on the basis of nonstatutory obviousness-type double patenting in view of claims 18-22 of US Patent No. 7,041,807 (Cashman).

- Cashman is not relevant because it discloses no blocking agent, modification of candidate polypeptide or detection agent, as recited in the present claims.
- Cashman method does not recite steps that obtain the same result as the present claims.

**Claim rejections – 35 USC 102**

Examiner has rejected claims 1-2, 9-17, 20-22, 29-30, 39, 41, 47-49 and 51 under 35 USC 102 as anticipated in view of US 2002/0123072 (Prusiner et al.; published 2002) and US 6,677,125 (Prusiner et al.; issued 2004; priority 2008).

- Discussion of teachings of prior art to differentiate them from pending claims. (not summarized in agenda for brevity)